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Original Article

Short-term clinical and quality-of-life outcomes in women treated by the TVT-Secur procedure

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Background: The TVT-Secur (Ethicon, Somerville, NJ, USA) is a minimally invasive suburethral synthetic sling used in the treatment of female stress urinary incontinence. It claims to cause less postoperative pain and to enable performing in an office setting. However, this may be at the expense of a significant learning curve and a higher early failure rate.
Aims: To assess objectively the success rate of the TVT-Secur procedure in the 'U' configuration at six months. Secondary outcomes focussed on subjective success rates, complications, patient satisfaction and quality-of-life (QOL).
Methods: A prospective observational study was undertaken at two tertiary referral urogynaecology centres. A cohort of 42 consecutive patients with urodynamic stress incontinence who underwent the TVT-Secur procedure in the 'U' configuration between November 2006 and August 2007 were followed up for six months. Three standardised QOL questionnaires were completed preoperatively and at six months. A urogenital history, visual analogue score (VAS) for patient satisfaction, uroflow and urinary stress test were performed at six months.
Results: Recruitment was ceased prematurely because of a high number of early failures. Objective and subjective success rates at six months were 58.3% and 51.3% respectively. Complications included urinary tract infections, voiding difficulty, groin discomfort, haematoma, vaginal pain, tape erosion and intra-operative dislodgement of tape. Prevalence of *de novo* urge incontinence was 10.3%. Only symptom-specific QOL scores improved and only 48.6% indicated a high level satisfaction (VAS ≥ 80%) with TVT-Secur.
Conclusion: On the basis of this limited study, we are hesitant to recommend the 'U' configuration of the TVT-Secur over its more established counterparts, the TVT and TVT-O.

Key words: stress incontinence, TVT, TVT-O, TVT-Secur.

Introduction

The TVT-Secur (Ethicon, Somerville, NJ, USA) is an 'exit-less' minimally invasive suburethral synthetic sling used in the treatment of female stress urinary incontinence. This approach claims to cause less postoperative pain and allows the surgeon to perform this procedure in an office setting.[1,2] The TVT-Secur can also be used in either retropubic (U) or transobturator (Hammock) configuration. This, however, may be at the expense of a significant learning curve and a higher early failure rate.[3]

The primary aim of this study was to assess prospectively the objective success rate (as demonstrated by a negative urinary stress test six months following surgery) of the TVT-Secur procedure in the 'U' configuration. Secondary outcomes assessed were the subjective success rates and the safety and efficacy of this device focussing on complications, patient satisfaction with surgery and impact on patients' quality of life (QOL) at six months.

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Methods

This was a prospective analysis of 42 consecutive patients undergoing the TVT-Secur procedure at two tertiary referral urogynaecology units. All patients were informed of the lack of long-term data available and potential risks and advantages of this procedure before consenting to participate in this study. The initial study design was intended to include 100 consecutive patients. However, recruitment was ceased prematurely because of a high number of early failures. Formal ethics committee approval was not required for this study as it was categorised as a clinical audit. The local research and ethics committee therefore provided an ethics committee waiver for this study.

Patients underwent preoperative urodynamic testing, which confirmed stress urinary incontinence in 100% of patients. Seventeen patients (40.5%) had isolated stress urinary incontinence, 25 patients (59.5%) were symptomatic of mixed urinary incontinence and 13 patients (31%) demonstrated detrusor overactivity on urodynamic testing. Urodynamic testing included measures of urinary flow rate,

post-voiding residual volumes and multichannel cystometry, which included provocative manoeuvres to demonstrate incontinence.

The TVT-Secur procedures were performed in U fashion. First, a paraurethral dissection plane is made from a suburethral incision. The bladder is emptied and a large urethral catheter and catheter guide is then inserted to deflect the urethra in the opposite direction of the tape insertion. The arm of the device is grasped with needle holders and inserted along the paraurethral dissection plane before being directed in a retropubic fashion 'hugging the pubic bone'. This is performed bilaterally, with the tension of the tape being determined by the depth of insertion of the second arm of the device. The ideal tension with which the tape was placed was judged subjectively to be slightly tighter than TVT or TVT-O tape placement. Cystoscopy was then performed to exclude urethral and bladder injury. The suburethral incision was then closed with a continuous 2/0 polyglactin suture. All but one procedure was performed under a general anaesthesia with additional local anaesthetic infiltration in the paraurethral dissection plane.

All procedures were performed or supervised by two experienced urogynaecologists who had previously received training in the TVT-Secur procedure and had performed no less than five TVT-Secur procedures before the commencement of this study. Whilst there were a total of five surgeons participating in this study, all but five procedures were performed by the two most experienced surgeons.

Patients were evaluated six months postoperatively with a urogenital history and examination, a visual analogue score (VAS) for patient satisfaction (pertaining to the TVT-Secur procedure only), a uroflow study, a post-voiding residual volume, and a urinary stress test. Patients were advised to present with a comfortably full bladder for their urinary stress test. This test involved a series of provocative manoeuvres such as coughing in an erect and supine position to demonstrate the presence of stress urinary incontinence. A negative stress test was the objective measure of success used in this study.

Patients completed three standardised QOL questionnaires preoperatively and at six months postoperatively. These were the Short Urogenital Distress Inventory (SUDI), the Short Incontinence Impact Questionnaire (SIIQ), and the EuroQol Questionnaires. The SUDI & SIIQ Questionnaires are symptom-specific QOL questionnaires, whilst the EuroQol is a generic QOL questionnaire, which measures general QOL.

The primary outcome measure was the objective success rate of the TVT-Secur procedure, as demonstrated by a negative urinary stress test six months following surgery. Secondary outcome measures included subjective success rate of the TVT-Secur procedure, preoperative and postoperative comparison of urodynamic parameters, operative complications, postoperative symptomatology, QOL analysis and patient satisfaction at six months.

Statistical analysis was performed using SSPS 11 for windows (SSPS Inc., Chicago, IL, USA). Tests for significance were conducted using the *t*-test for normally distributed continuous variables and Wilcoxon Signed Ranks test for nonparametric analyses of QOL scores. Statistical analyses pertaining to success rates and prevalence of urge urinary incontinence were undertaken using Fisher's Exact test.

Results

Patients were followed up for a minimum duration of six months, but three patients were lost to follow-up at the six-month review. The mean age was 56.2 years (SD 9.96) and median parity was 3 (range 0–7). Thirty-one patients (73.8%) were menopausal and 17 of these patients (54%) were taking hormone replacement therapy. Of the 42 patients with stress urinary incontinence, 25 patients (59.5%) were symptomatic of concomitant urge incontinence and 13 patients (31%) demonstrated detrusor overactivity on preoperative urodynamics. Preoperative urodynamics also demonstrated a low maximal urethral closure pressure (MUCP < 20 cmH_20) in five patients (12%).

Seventeen patients (40%) had prior urogenital surgery. These included anterior vaginal repair (5), posterior vaginal repair (3), vaginal hysterectomy (1), abdominal hysterectomy (8), sacrospinous colpopexy (2). Six patients (14%) had previous incontinence surgery, one of whom had undergone two previous incontinence procedures. These included Burch colposuspension (3), mid urethral tape (3) and transurethral injection of a urethral bulking agent (1).

Concomitant surgery was performed in six patients (15%). These procedures included anterior vaginal repair (4), posterior vaginal repair (5), sacrospinous colpopexy (3).

Success rates and rates of complications are detailed in Tables 1 and 2 respectively. These were calculated as a percentage of the 39 patients who returned for follow-up at six months. The objective success rate was 58.3% and the subjective success rates were 51.3% at six months. There was no significant reduction in the prevalence of urge urinary incontinence following surgery (59.5% preoperatively and 61.5% at six months, $P = 1.0$). The prevalence of *de novo* urge urinary incontinence was 10.3% at six months. There were no significant differences between preoperative and postoperative uroflow parameters ($P = 0.57$) or

Table 1 Comparison of pre- and postoperative outcomes

Variable	Preoperative	Postoperative	*P*-value
SUI (%)	100	48.7	1.47
MUI (%)	59.5	38.4	0.08
UUI (%)	59.5	61.5	1.00
De novo UUI (%)		10.3	
Flow rate, Q_{max} (mean)	21.9 mL/s	20.8 mL/s	0.57
Residual urine (mean)	16.7 mL	18.1 mL	0.86
Voiding difficulty (%)	0	9.7	0.24
Subjective cure (%)		51.3	
Objective cure (%)		58.3	

MUI, mixed urinary incontinence; SUI stress urinary incontinence; UUI, urge urinary incontinence.

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Table 2 Operative and postoperative complications

Complication	No. cases	%
Voiding difficulty	3	7.7
Urinary tract infection	5	12.8
Haematoma	3	7.7
Groin discomfort	8	20.5
Vaginal tape erosion	3	7.7
Vaginal/suburethral pain	3	7.7
Tape dislodgement	2	5.0
Wound infection	0	0

post-voiding residual volumes ($P = 0.86$). However, there was a significantly lower subjective success rate of 0% ($P = 0.02$), and a non-significant trend towards a lower objective success rate of 20% ($P = 0.08$) in five patients with intrinsic sphincter deficiency.

The most prevalent complication was groin discomfort (eight patients, 20.5%) despite using the 'U' configuration. Culture proven urinary tract infection (UTI) was the next most prevalent complication, which occurred in five patients (12.8%). There were also three cases (7.7%) of voiding difficulty ($Q_{max} < 10$ mL/s and residual volume > 100 mL). Other complications included haematoma (three cases, 7.7%), paraurethral vaginal mesh erosion (three cases, 7.7%), paraurethral or suburethral vaginal pain (three cases, 7.7%) and intra-operative dislodgement of tape requiring re-insertion of tape arm (two cases, 5%). There were no cases of major vascular injuries, bladder injury or other visceral injuries.

Ten operations were required subsequent to the initial incontinence procedure, all but one relating to complications or failure of the TVT-Secur. In the first six months, seven patients (17.9%) required further anti-incontinence procedures. These included; TVT (three cases, 7.7%), TVT-O (two cases, 5.1%), transurethral injection of urethral bulking agent (one case, 2.6%) and pubovaginal sling (one case, 2.6%). Three patients (7.7%) required excision of a para-urethral vaginal mesh erosion from the TVT-Secur. One patient developed a rectocele and underwent a posterior colporrhaphy.

Quality-of-life analysis revealed a significant improvement in mean SUDI and SIIQ scores ($P < 0.001$), but no significant improvement in Euroqol scores at six months ($P = 0.637$). In fact, only 43.2% reported an improved general state of health compared to the previous 12 months on the postoperative Euroqol questionnaire. In addition, VAS at six months indicated high patient satisfaction (VAS ≥ 80%) in only 48.6% of patients.

Discussion

This study indicates that the TVT-Secur is limited by a high early failure rate which may be related to a long learning curve. Our objective success rate of 58.3% and subjective success rate of 51.3% at six months were not dissimilar to the 62% objective success rate reported by Martan *et al.*[4] This fell well short of the success rates reported for the TVT (81–96%) and TVT-O or similar transobturator tapes (80–90%).[5–19] In Martan's study, the low success rate of the TVT-Secur was irrespective of tape placement (U or hammock).[4] Despite a subjectively tighter placement of the TVT-Secur tape in our study, failure rates were high. A possible explanation for this is demonstrated by Martan *et al.*'s ultrasound findings which indicate that the low success rate may be caused by a weakening of the restriction of urethral mobility by the tape within the first three months.[4] Whilst other studies investigating the TVT-secur have achieved higher success rates in the order of 80–100%, most of these studies were limited by small patient numbers and/or a short duration of follow-up.[1–4,11,20] To date, there have not been any comparative studies between the TVT-Secur and other midurethral tapes such as the TVT or the TVT-O. Further comparative studies of this nature would be needed before any definitive conclusions can be drawn about the relative safety and efficacy of the TVT-Secur.

In addition to this, the TVT-Secur procedure failed to reduce the prevalence of urge incontinence. The preoperative prevalence of urge incontinence of 59.5% was similar to the postoperative prevalence of 61.5% at six months. This is in contrast to the significant reduction in prevalence of urge incontinence previously reported with the TVT and TVT-O.[7,14,15,21] However, the prevalence of *de novo* urge incontinence in our series of 10.8% was similar to the rates reported with the TVT (5.8–15%) and TVT-O (4.8–8%).[7,13–15,17,18,22–25]

There was also a significantly lower subjective success rate of 0% ($P = 0.02$) and a non-significant trend towards lower objective success rates of 20% ($P = 0.08$) amongst patients with preoperative intrinsic sphincter deficiency (MUCP < 20 cmH_20). However, there was no significant difference between preoperative and postoperative urinary flow parameters or post-voiding residual volumes in our study.

When comparing overall complication rates associated with the TVT-Secur procedure with that of the TVT or TVT-O procedures, the TVT-Secur did not appear to offer any significant advantage over its more established counterparts.[6,7,9,11,12,14,17–19,22–28]

The most prevalent complication or complaint in this series was groin pain or discomfort (20.5%) within the first six months despite all the procedures being performed in a retropubic 'U' fashion. None of the affected patients in our series had sought further treatment for this problem by the six-month review indicating either a spontaneous resolution by the six-month review or a low level of persistent discomfort. This compares with a reported rate of 2.7–24% with the TVT-O procedure and 1% for the TVT reported by Duckette and Jain.[6,7,26,29–31]

The prevalence of postoperative voiding difficulty with the TVT-Secur (9.7%) was similar to the 4–22.6% reported with the TVT, but higher than the 1.6–4% reported with the TVT-O.

The incidence of UTIs in the first six postoperative months in this series was 12.8%. This was also comparable with the reported UTI rates for the TVT (4–22%) and the

TVT-O (2–15.5%).[7,13,14,18,19,27,31,32] Whilst bladder injury is the most common intra-operative complication reported with the TVT occurring in 3.8–9.7% of cases, there were no such injuries in our series, which is similar to bladder injury rates reported for the TVT-O.[7,14,16–18,22–24,26–28,32,33] Whilst it should be noted that the small numbers in our series precludes us from accurately determining the real risk of bladder injury with this procedure, other studies have demonstrated a bladder injury rate of 0–1% with the TVT-Secur.[3,11]

There were no cases of vascular or other visceral injuries in our study. These results are consistent with other studies of TVT-Secur procedure.[3,11,20]

There were no cases of intra-operative haemorrhage in our series, but there were two cases (5.1%) of retropubic haematomas and one case (2.5%) of a peri-urethral haematoma. This compares with a pelvic haematoma rate of 0.6–1.9% and a 'significant' intra-operative blood loss in 0.9–5.4% with the TVT and a haematoma rate of 0–1.1% with the TVT-O.[6–8,18,22,25,27,30,32,33] There were no cases of superficial wound infection in our series compared with 0.4–2% reported for the TVT and 1.1–2% for the TVT-O.[7,14,18,22,27,33]

Although the mesh erosion rate of 7.7% in our series was considerably higher than the 0.4–4.1% reported with the TVT and TVT-O, it was not out of keeping with the 0.9–12% reported in other studies investigating the TVT-Secur procedure.[3,7,11,14,18,22,24,25,32]

All three mesh erosions in this series failed conservative management and were subsequently treated by surgical excision of the exposed TVT-Secur mesh. Given that other studies have reported a 33–50% incontinence rate following tape division and a 30% requirement for further anti-incontinence surgery, it was not unexpected that one of the three patients developed stress incontinence after excision of the mesh erosion.[25,34] This patient required a further TVT-O procedure. One patient remained continent after the mesh erosion was surgically excised and one patient did not achieve continence even before the mesh erosion was excised.

In all, seven patients required a further anti-incontinence procedure to treat their stress incontinence. Three patients underwent a further TVT, two underwent a further TVT-O procedure, one patient required a transurethral injectable bulking agent and the remaining patient required a pubovaginal sling. Six of the seven additional anti-incontinence procedures were successful at the six-month review, whilst the remaining TVT-O case had not yet been reviewed following her secondary procedure.

Three patients (7.7%) reported vaginal or suburethral pain following the TVT-Secur procedure. One patient was subsequently diagnosed with paraurethral vaginal mesh erosion, another was subsequently diagnosed with interstitial cystitis and no cause could be found for the remaining patient. Whilst the vaginal pain was successfully treated by excision of the mesh erosion for one patient, the suburethral and vaginal pain persisted in the other two patients.

In our series, there were two cases (5.1%) where the TVT-Secur arms were dislodged and required re-application intra-operatively. This is not unique to our series as it was also reported in five cases (10%) in a series by Neuman[3] in their early cases.

Comparisons of the preoperative and postoperative QOL questionnaires revealed a significant improvement in symptom-specific QOL scores (ie SUDI & SIIQ) at six months, but failed to yield any significant improvement in the generic QOL questionnaire (Euroqol). This was reflected in the low levels of 'high patient satisfaction' (VAS ≥ 80%) achieved at six months (48.6%), and low percentage (43.2%) of patients reporting an overall improvement in their general state of health following surgery.

Conclusion

In the short-term, the TVT-Secur procedure appears to have fallen short of its counterparts, the retropubic TVT and the transobturator TVT-O. Six-month subjective and objective cure rates for stress incontinence were much lower than those reported for the TVT and TVT-O procedures, and for the most part, complication rates were no better and sometimes worse than the TVT or TVT-O procedures. Whilst symptom-specific QOL data suggest a positive impact following this procedure, generic QOL data and VAS of patient satisfaction were disappointing. On the basis of this limited study, we would be hesitant to recommend the 'U' configuration of the TVT-Secur procedure over its more established counterparts, the TVT and TVT-O.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1 Short incontinence impact questionnaire (SIIQ)

Appendix S2 Short urogenital distress inventory (SUDI).

Appendix S3 Euroqol patient questionnaire.

Appendix S4 Visual analogue scale.

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